

APPLICANTS:
U.S.S.N.:

Nathan H. Sloane
09/986,606

REMARKS

In response to the Notice of Improper Request for Continued Examination (RCE), Applicant hereby submits this response under 37 C.F.R 1.114. Applicant thanks Examiner Low for the telephone conference in which a proper response the Notice was discussed. Examiner Low acknowledged that the due date for responding to the Notice is one month from the mailing of the Notice. Applicant therefore requests entry of the present amendment, which is responsive to the Office Action mailed on December 19, 2001. The substantive text of the office action is recited in the office action mailed on September 17, 1998.

Claims 4-15 are pending, claims 1-3 having been canceled and new claims 4-15 having been added. New claim 1 is supported by disclosure on page 3, lines 2-29 of the specification. New claims 5-7 are supported by disclosure throughout the specification, e.g., on page 4, line 1, to page 5, line 12. New claims 8-12 are supported by disclosure on page 2, lines 1-10, and on page 3, lines 10-17, of the specification. New claims 12-15 are supported by disclosure at page 2, lines 10-13, and on page 5, lines 1-12, of the specification .

The specification was amended to insert a SEQ ID NO and to correct a typographical error (single-letter code for cysteine is "C" rather than "S").

No new matter has been added by this amendment.

35 U.S.C. § 102

Claims 1-3 were rejected for anticipation by Ridge et al. Claims 1-3 were canceled, and new claims 4-15 were added. Applicants submit that the new claims are distinguished from the cited prior art.

Ridge et al. describe an amino acid sequence of anti-neoplastic urinary protein (ANUP). The sequence is a 15- amino acid sequence: pyroglutamate- Leu-Lys-X-Tyr-Thr-X-Lys-Glu-Pro-Met-Thr-Ser(Thr)-Ala-Ala. In contrast, claims 4, 5, 8-11, and 15 require the amino acid sequence of SEQ ID NO:1. SEQ ID NO:1 specifies 16 amino acids: pyroglu-Leu-Lys-Cys-Tyr-Thr-Cys-Lys-Glu-Pro-Met-Thr-Ser-Ala-Ala-Cys. The sequence required by the amended claims is longer and contains a cysteine residue at position 16. Ridge et al. fail to describe a 16 amino acid sequence and fail to disclose the precise amino acid sequence now required by the amended claims. Applicant therefore requests withdrawal of this rejection.

New claims 6, 7, and 12-15 require activation of an anti-tumor peptide, e.g., a peptide containing the amino acid sequence of SEQ ID NO:1, with a detergent such as sodium dodecyl sulfate. Ridge et al. do not describe a detergent, nor do these researchers describe activation of an anti-tumor property of a peptide by contacting the peptide with a detergent, as now required by the claims. Therefore, Applicant submits that these claims are not anticipated by the cited reference.

35 U.S.C. § 101

Claims 1 and 3 were rejected under §101 "because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101".

Claims 1 and 3 were canceled. New claims 8-11 are drawn to methods of using a polypeptide containing the amino acid sequence of SEQ ID NO:1, and new claims 12-15 are drawn to methods of activating an anti-tumor peptide. Applicant submits that the format of the new methods claims fulfills the requirements of §101, and therefore, requests withdrawal of this rejection.

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35 U.S.C. § 112

Claim 1 was rejected for indefiniteness for recitation of the phrase "using the human breast tumor cell as a model". The Examiner also objected to the claim term "antineoplastic protein". Claim 1 has been canceled, and new claims 4-15 have been added. The claim terms to which the Examiner objected are not recited in the new claims. This rejection can now be withdrawn.

Sequence Listing

A Sequence Listing for the amino acid sequence (SEQ ID NO:1) disclosed in the specification, in compliance with the requirements of 37 C.F.R. §§ 1.821-1.825 is concomitantly filed.

CONCLUSION

On the basis of the foregoing arguments and amendments, Applicant respectfully submits that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact any of the undersigned at the telephone number provided below.

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The Commissioner is hereby authorized to charge any additional fees that may be due,
or credit any overpayment of same, to Deposit Account No. 50-0311 (Reference No. 21578-013).

Respectfully submitted,



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Appendix: Marked up version of amended claims

In the specification:

On page 2, delete the paragraph spanning lines 15-32 and replace with the following amendment:

The ANUP N-terminal 16 amino acid peptide contains the following sequence (as L-Amino Acids):

1. Pyroglu
2. Leu
3. Lys
4. Cys
5. Tyr
6. Thr
7. Cys
8. Lys
9. Glu
10. Pro
11. Met
12. Thr
13. Ser
14. Ala
15. Ala
16. Cys (SEQ ID NO:1)

On page 3, delete the paragraph spanning lines 20-29 and replace with the following amendment:

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The synthetic hexdeca peptide (16 L-amino acids) has the following sequence:

1. Pyroglu		9. Glu	E
2. Leu	L	10. Pro	P
3. Lys	K	11. Met	M
4. Cys	[S] <u>C</u>	12. Thr	T
5. Tyr	Y	13. Ser	S
6. Thr	T	14. Ala	A
7. Cys	C	15. Ala	A
8. Lys	K	16. Cys	C (SEQ ID NO:1)

In the claims:

Cancel claims 1-3. Add new claims 4-15.

- 4. A purified polypeptide comprising the amino acid sequence of SEQ ID NO:1.--
- 5. An anti-tumor agent, comprising an apoptosis-inducing concentration of a polypeptide, wherein said polypeptide comprises the amino acid sequence of SEQ ID NO:1.--
- 6. The agent of claim 5, wherein said anti-tumor agent is activated by contacting said polypeptide with a detergent.--
- 7. The agent of claim 6, wherein said detergent is sodium dodecyl sulfate.--
- 8. A method of killing a tumor cell, comprising contacting said tumor cell with a polypeptide comprising the amino acid of SEQ ID NO:1.--
- 9. The method of claim 8, wherein said tumor is a breast tumor.--

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--10. The method of claim 8, wherein said tumor is a cervical tumor.--

--11. The method of claim 8, wherein said tumor is a laryngeal tumor.--

--12. A method of activating an anti-tumor polypeptide, comprising contacting said polypeptide with a detergent, wherein said an anti-tumor activity of said polypeptide is activated after said contacting step.--

--13. The method of claim 12, wherein said anti-tumor activity comprises killing by apoptosis.--

--14. The method of claim 12, wherein said detergent is sodium dodecyl sulfate.--

--15. The method of claim 12, wherein said polypeptide comprises the amino acid sequence of SEQ ID NO:1.--

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